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Review Article

How are normal sleeping controls selected? A systematic review of cross-sectional insomnia studies and a standardized method to select healthy controls for sleep research

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ABSTRACT

There appears to be some inconsistency in how normal sleepers (controls) are selected and screened for participation in research studies for comparison with insomnia patients. The purpose of the current study is to assess and compare methods of identifying normal sleepers in insomnia studies, with reference to published standards. We systematically reviewed the literature on insomnia patients, which included control subjects. The resulting 37 articles were systematically reviewed with reference to the five criteria for normal sleep specified by Edinger et al. [2]. In summary, these criteria are as follows: evidence of sleep disruption, sleep scheduling, general health, substance/medication use, and other sleep disorders. We found sleep diaries, polysomnography (PSG), and clinical screening examinations to be widely used with both control subjects and insomnia participants. However, there are differences between research groups in the precise definitions applied to the components of normal sleep. We found that none of the reviewed studies applied all of the Edinger et al. criteria, and 16% met four criteria. In general, screening is applied most rigorously at the level of a clinical disorder, whether physical, psychiatric, or sleep. While the Edinger et al. criteria seem to be applied in some form by most researchers, there is scope to improve standards and definitions in this area. Ideally, different methods such as sleep diaries and questionnaires would be used concurrently with objective measures to ensure normal sleepers are identified, and descriptive information for control subjects would be reported. Here, we have devised working criteria and methods to be used for the assessment of normal sleepers. This would help clarify the nature of the control group, in contrast to insomnia subjects and other patient groups.

1. Introduction

Given the significance of sleep to well-being [1], consistency in how research participants are selected is important. Indeed, this is accepted among clinicians, with diagnostic systems used to identify different sleep disorders [2–4]. While it is acknowledged that adherence to consensus categorization systems is important with clinical groups, such high standards have not always been applied to the selection of normal sleepers (controls). As a result, the precise definitions, and consequently methods, applied to identify normal sleepers are variable within sleep research. The purpose of the current study was to investigate exactly how control subjects are assessed, in comparison to insomnia patients. The selection of control subjects is important, as group differences may be caused by these subjects rather than the patient group, if normal sleepers are not well defined and selected. Furthermore, consistency in how normal sleepers are defined is important in order to compare results between studies. These results have broader implications for the selection of normal sleepers or control subjects within sleep research overall.

A definition of normal sleepers (controls) has been provided, and five criteria have been identified. The research diagnostic criteria (RDC) for normal sleepers specifies that normal sleepers should show no evidence of sleep disruption (Criterion A) and that the timing of sleep should be both regular and conventional (Criterion B) [2]. As such, both the quality of sleep and its timing are thought to be important in defining normal sleepers. However, these components of normal sleep are not always applied in practice. For example, the Pittsburgh Sleep Quality Index (PSQI) [5], and the Insomnia Severity Index (ISI) [6], have been used to categorize participants as poor and normal sleepers [7–11]. In this approach, those participants scoring below threshold are categorized as normal sleepers.

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Others seem to define acceptable levels of sleep disruption or to select healthy subjects based on the absence of insomnia disorder rather than the presence of normal or good sleep. However, such differences in methods may lead to different groups being used as a comparison, with some subjects being better sleepers than others. Furthermore, evidence of sleep disruption is only one component of research diagnostic criterion for control subjects [2].

The second component of research diagnostic criterion for control subjects includes two elements. First, sleep timing is conventional [2]. Some authors specify habitual bedtimes and rise times as inclusion criteria. This is also pertinent to circadian rhythm sleep disorders (CRSDs), and an individual's preference for morningness or eveningness is relevant to their sleep scheduling. The morningness–eveningness questionnaire (MEQ) was developed to assess diurnal preference [12], and it has been used to identify morning and evening types [13–17]. Second, the RDC also specifies that the timing of sleep is stable. Sleep diaries can be used to monitor adherence to a sleep schedule [15,18,19], and assess reported sleep patterns and habits, as well as their variability [20–22]. They provide information about the daily timing of sleep, as well as measures of sleep continuity (eg, wake after sleep onset), and its qualitative experience, and sleep diaries are regarded as the "gold standard" in measuring subjective sleep experience [23]. However, while a routine sleep schedule is thought to be important to normal sleep [24,25], there seems to be a lack of clarity as to how much variability in sleep scheduling is acceptable in practice.

To fully understand the development and maintenance of sleep disorders, such as insomnia, it is necessary to understand the processes in normal sleep [24–26]. However, this is hampered when the methods of assessment of normal sleepers differ, and this seems especially pertinent when research subjects are recruited from a student population, whose sleep can be irregular and of poor quality [27]. A majority of potential participants (ie, normal sleepers) might be expected to show a moderate level of vulnerability towards poor sleep or insomnia, in keeping with a normal distribution (eg, Yiend [28]). When insomnia subjects and normal sleepers are compared on the effects of poor sleep, the daytime effects of poor sleep are similar, although more severe for insomnia patients [29], and both groups use comparable criteria to judge sleep quality [30]. However, in insomnia patients, the daytime effects associated with sleep seem especially important, both in theory [25,31] and to patients themselves [29,32]. Current research is aimed at investigating the etiology of insomnia disorder, for example, the development of chronic insomnia from acute insomnia [33], and this suggests the importance of additional factors in the development of insomnia disorder. For example, insomnia patients might experience the effects of sleep disruption more severely or report more frequent nights of poor sleep [28], and changes in sleep architecture could contribute towards this transition [33]. Furthermore, in keeping with a normal distribution [28], some normal sleepers could show evidence of sleep disruption, while not quite endorsing insomnia (eg, Ref. [25]). Normal sleepers could also be different from good sleepers, who would be expected to report good sleep without sleep disruption. Although investigating the differences between good sleep and normal sleep is beyond the scope of the current paper, understanding definitions applied to control subjects seems an important first step. As such, we have conducted a systematic review on how control subjects are assessed for study inclusion within insomnia research. We then outline recommendations for assessing normal sleep, and we suggest methods of assessment.

2. Methods

A literature search was conducted within six key sleep society-affiliated journals. In particular, *Sleep* is the official publication of the Associated Professional Sleep Societies, the *Journal of Sleep Research* is published on behalf of the European Sleep Research Society, and *Sleep Medicine* is the official journal of the World Association of Sleep Medicine and International Pediatric Sleep Association. *Behavioral Sleep Medicine* is the official journal of the Society of Behavioral Sleep Medicine; *Chronobiology International* is the official journal for the International Society for Chronobiology, the American Association for Medical Chronobiology and Chronotherapeutics, and the Society for Light Treatment and Biological Rhythms. The *Journal of Biological Rhythms* is the official publication of the Society for Research on Biological Rhythms. The *Journal of Clinical Sleep Medicine*, an official publication of the American Academy of Sleep Medicine, was not included due to a lack of institutional access. The literature search was confined to these journals, as they were expected to apply more stringent criteria towards how sleep groups are defined. The anticipated effect of this was to bias the literature search towards more conservative or stringent methodologies with respect to sleep.

The "Web of Knowledge" (http://wok.mimas.ac.uk/) search engine was used to access database entries for these journals. The key search terms were "poor sleep" or "insomnia," and a large number of results were found initially (24,782 search results). These results were filtered by selecting article types that were published in English, and we selected those studies based on adults (see Fig. 1). We further refined these results to identify those papers where an insomnia sample was compared against controls, and 64 abstracts were then manually reviewed (Fig. 1). These papers were all published from 2005 until present, following the publication of the RDC in 2004. As the focus of this review was on methods of assessment, sample size was not considered as an exclusion criterion.

Papers without a suitable control group were excluded (eg, intervention studies), giving a final sample of 37 (Table 1). All papers included an insomnia patient group, and the majority (30) used patients with primary insomnia. Data were extracted by selecting those methods relevant to each of the five criteria in the RDC [2]. In general, specific details as to insomnia and methods of sleep assessment were coded within Criterion A. Information relevant to CRSDs and test time, as well as work and travel, was contained within Criterion B. In keeping with the RDC, methods relevant to physical and psychiatric health, medication use and substance abuse, and sleep disorders in general were coded separately under Criteria C, D, and E. All data were coded as described in the original papers, and not subject to interpretation at initial encoding.

3. Results

3.1. Criterion A

We recorded how control groups were defined with regard to Criterion A, that is, "the individual has no complaints of sleep disturbance or daytime symptoms attributable to unsatisfactory sleep." First, the definitions applied to control subjects are summarized. These definitions varied from "healthy" to "normal/good sleepers" to "typically good sleepers," and they included descriptions such as no subjective complaints of sleep difficulties or insomnia, or sleep or insomnia complaints. More detailed definitions included subjects characterizing their sleep as restorative or refreshing, sleep satisfaction, relatively imperturbable sleep, and falling asleep as soon as their head touches the pillow. Additional specifications included that subjects report no history of sleep disorders or insomnia, either currently or in the past, and objective sleep thresholds were also used. Sleep questionnaires can be used to quantify sleep-related thresholds, and 5% of studies reported cutoff scores or descriptive information for the PSQI, with the ISI similarly used by 30% of papers. Many studies (51%) reported sleep diary

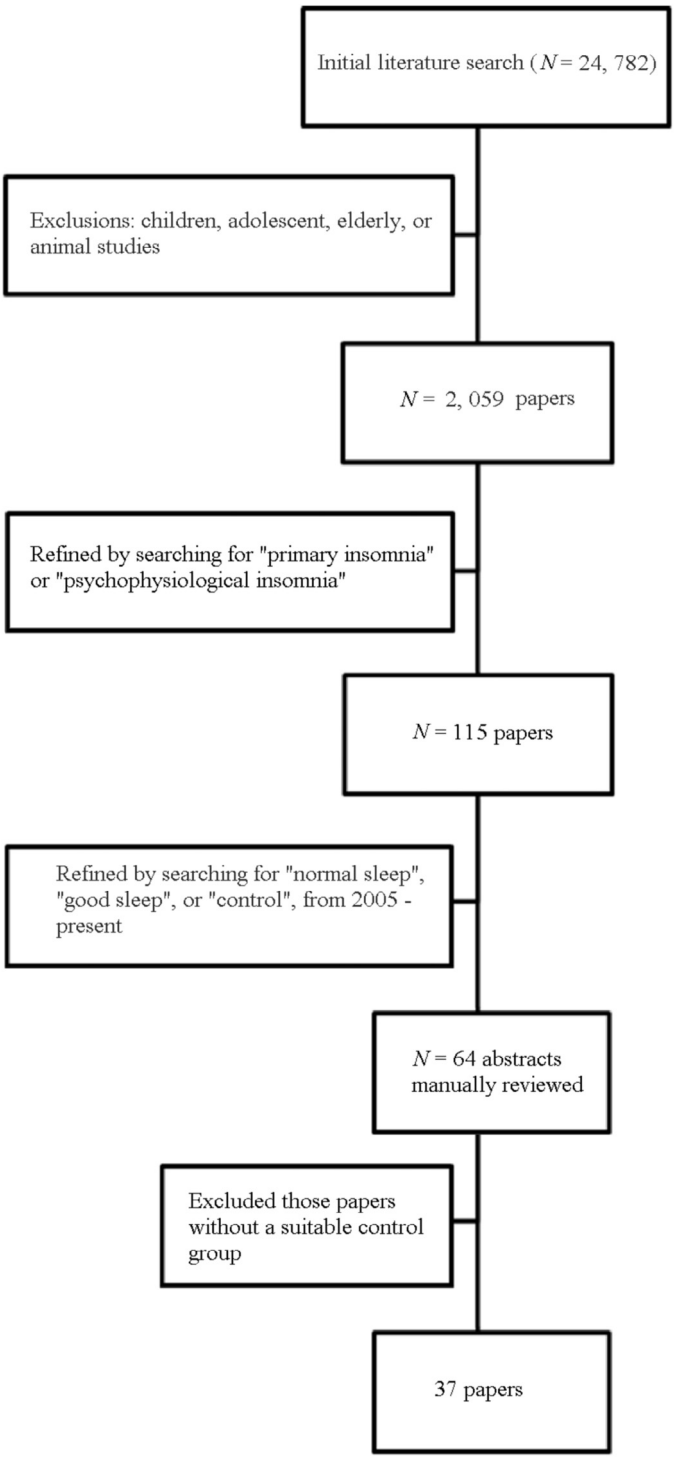

Fig. 1. Literature search strategy.

parameters of control subjects, and a majority of studies (65%) reported descriptive sleep information from polysomnographic (PSG) measures, with two studies (5%) reporting actigraphy-derived sleep parameters.

In terms of meeting Criterion A, we required papers to have explicit exclusion criteria based on both measures of sleep disruption (i.e., sleep continuity) and daytime effects (eg, report sleep as restorative). In total, 8% of papers met this criterion.

3.2. Criterion B

Criterion B is defined as an individual having "a routine standard sleep/wake schedule characterized by regular bedtimes and rising times." To assess this, we recorded information relevant to sleep timing within the articles. Four studies (11%) reported average bedtimes/rise times, and the range of subjects' sleep timing was reported by 30% of studies, either descriptively or as inclusion criterion (eg, to confirm consistency of habitual sleep patterns with a specified sleep laboratory schedule). One study reported an actigraphy-derived measure of the circadian phase, and another reported a measure of diurnal preference. Other relevant exclusion criteria included shift-working patterns and long-range travel, as well as CRSDs or abnormal usual sleep schedules. With regard to meeting criteria for sleep timing, adherence to this criterion was defined by explicit exclusion criteria for sleep timing, that is, bedtimes and rise times, and met by 30% of papers.

3.3. Criterion C

Criterion C is defined as "no evidence of a sleep-disruptive medical or mental disorder."

A majority of studies applied general medical examinations, which were used to assess health, and the absence of signs or symptoms of a disorder (eg, blood screening tests). Twelve studies (32%) also reported body mass index (BMI) scores, and 56% used or reported data from additional questionnaire screening measures for symptoms of mental health conditions, such as depression or anxiety. At least one medical condition was excluded for by 84% of studies, and specific disorders listed included unstable hypertension, thyroid disorders, seizure disorders, neurodegenerative disease, chronic pain, significant head trauma or loss of consciousness, cardiovascular or respiratory disease, diabetes, dementia, multiple sclerosis, pregnancy, hepatitis, cancer, Parkinson's disease, rheumatoid arthritis, gastroesophageal reflux disease, asthma, and chronic obstructive pulmonary disease. At least one psychiatric disorder was excluded for by 86% of studies, which included mood disorders, psychotic disorders, anxiety disorders, eating disorders, somatoform disorders, and substance abuse disorder (the latter is considered in more detail under Criterion D). When this criterion was judged via exclusions for medical and psychiatric disorders, 70% of papers met this criterion.

3.4. Criterion D

Criterion D is defined as "no evidence of sleep disruption due to a substance exposure, use, abuse, or withdrawal." Generally, articles assessed subjects for evidence of a disorder that would be relevant to this criterion. In total, 76% of articles reported exclusion criteria as to medication use, and these articles most commonly selected subjects who were not on medication, not using medication affecting sleep, or taking CNS-active agents, psychotropic agents, or hypnotics. Drug abuse or dependence was excluded by 57% of studies, with alcohol, caffeine, or nicotine consumption mentioned by 59% of articles. When D was defined as explicit exclusions for substance abuse and medication use, 43% of studies met criterion.

3.5. Criterion E

The final criterion is "no evidence of a primary sleep disorder." A number of studies (59%) reported PSG screening for sleep apnea and limb movements in control subjects. Evidence of sleep disruption, or other sleep disorders, was assessed by 76% of articles and included evidence of current disorder, evidence of symptoms, and/or past (or family) history. In addition, other disorders (e.g., nocturia, enuresis, and bruxism) were mentioned occasionally. When this

Table 1
Summary of papers meeting inclusion criteria.

	First Author	Year	Control N	Age	Gender	Insomnia patients
1	Bastien	2013	30	35.8 (9.1)	18 F, 12 M	Psychophysiological insomnia, paradoxical insomnia
2	Huang	2012	48	38 (12)	28 F, 20 M	Primary insomnia
3	Israel	2012	22	26.5 (7.3)	19 F, 3 M	Primary insomnia
4	Morgan	2012	17	36 (9)	9 F, 8 M	Primary insomnia
5	Corsi-Cabrera	2012	10	25.6 (4.6)	5 F, 5 M	Primary insomnia
6	Forget	2011	12	44.3 (9.4)	7 F, 7 M	Primary insomnia
7	De Zambotti	2011	8	23.23 (3.24)	5 F, 3 M	Primary insomnia
8	Nissen	2011	53	46.9 (4.65)	32 F, 21 M	Primary insomnia
9	Spiegelhalder	2011	46	37.3 (11.4)	27 F, 19 M	Primary insomnia
10	Manconi	2010	288	58.5 (7.23)	176 F, 112M	Primary insomnia
11	Winkelman	2010	15	38.8 (5.3)	6 F, 9 M	Primary insomnia
12	Deuschle	2010	827	54.6 (17.2)	455 F, 372 M	Primary insomnia
13	Spiegelhalder	2010	30	48.3 (12.9)	21 F, 9 M	Primary insomnia
14	Parrino	2009	20	45 (8)	16 F, 4 M	Paradoxical insomnia
15	Lanfranchi	2009	13	42 (9)	9 F, 4 M	Primary insomnia
16	Buysse	2008	25	30.6 (7.4)	15 F, 10 M	Primary insomnia
17	Winkelman	2008	16	37.6 (4.5)	7 F, 9 M	Primary insomnia
18	Feige	2008	100	41.12 (13.99)	54 F, 36 M	Primary insomnia
19	Spiegelhalder	2008	20	38.6 (10.1)	12 F, 8 M	Primary insomnia
20	Bastien	2008	16	36.81 (10.19)	10 F, 6 M	Psychophysiological insomnia
21	Edinger	2008	84	48.6 (16.8)	41 F, 43 M	Primary insomnia
22	Sagaspe	2007	13	45 (12)	5 F, 8 M	Psychophysiological insomnia
23	Orff	2007	17	36.1 (7.1)	13 F, 4 M	Primary insomnia
24	Riemann	2007	8	46.3 (14.3)	5 F, 3 M	Primary insomnia
25	Robertson	2007	15	27.7 (7.05)	8 F, 7 M	Psychophysiological insomnia
26	Yang	2007	15	34.3 (12.9)	10 F, 5 M	Primary insomnia
27	Buysse	2007	18	27.2 (7.9)	15 F, 3 M	Primary insomnia
28	MacMahon	2006	20	28.2 (10.1)	11 F, 9 M	Primary insomnia
29	Ouellet	2006	14	30.00 (10.05)	5 F, 9 M	Insomnia syndrome (DSM-IV and ICSD)
30	Nissen	2006	7	44.9 (4.1)	4 F, 3 M	Primary insomnia
31	Marchetti	2006	30	23.2 (1.69)	15 F, 15 M	Psychophysiological insomnia
32	Carney	2006	104	47.3 (16.8)	52 F, 52 M	Primary insomnia
33	Lineberger	2006	88	45.39 (16.59)	44 F, 44 M	Primary insomnia
34	Rioux	2006	11	48.00 (7.86)	5 F, 6 M	Primary insomnia
35	Salin-Pascual	2006	6	26.6 (5.0)	4 F, 2 M	Primary insomnia
36	Thacher	2006	10	34.7 (7.9)	7 F, 3 M	Primary insomnia
37	Devoto	2005	7	22.6 (2)	4 F, 3 M	Primary insomnia

criterion was defined as explicit exclusion criteria for sleep disorders in conjunction with PSG, 54% of papers met criteria.

In total, no papers were judged to meet all five criteria. Sixteen percent met four criteria, 24% of papers met three criteria, 27% met two criteria, and 14% met one criterion, with 19% of papers meeting none. The complete table as to how papers were coded is available online in Appendix S1.

4. Discussion

Overall, the selected articles screened subjects well for potential disorders (whether physical, psychiatric, or sleep). However, the criteria applied to control subjects differed between studies, and information relevant to criteria seemed to be used to describe subject groups, rather than as explicit a priori exclusion criteria. There are also differences between laboratories as to how exactly subjects are identified, and Criteria A and B seem to require clarity. While Edinger et al. [2] define A as "no complaints of sleep disturbance, or daytime symptoms attributable to poor sleep," there is a lack of consensus as to how exactly this should be defined. For example, some specify sleep diary criteria, while others use questionnaire cutoffs, and/or a lack of "sleep complaint," or absence of insomnia disorder as such. We would interpret A as comprising three main elements: first, whether an individual is experiencing sleep disturbance (ie, via sleep duration or sleep continuity measures); second, whether subjects are satisfied with their sleep and experience good sleep quality; and third, the experience of adverse sleep-related daytime effects leading to the exclusion of control subjects.

Criterion B, defined as "a routine standard sleep/wake schedule characterized by regular bedtimes and rising times," [2] seems to comprise several components, in particular, the habitual timing of sleep and its stability. Evidence of CRSDs often seemed to be used to assess this criterion, overlapping with Criterion E. While a majority of authors reported the use of sleep diaries, which can be used to assess this, it is often unclear exactly how these components are defined in practice. Many authors defined normal sleep timing parameters, although normality would seem to depend on the study sample and would be affected, for example, by age [34]. Sleep timing, chronotype, and sleep quality seem to be interlinked [35–37]. Furthermore, while the stability of sleep timing seems to be important for control subjects, this component seems to be rarely directly addressed, other than by shift work, and it is unclear whether any exclusions were made based on sleep timing stability as such. The variability, or stability, of sleep timing could also contribute to good sleep (eg, Ref. [25]), and differences in sleep timing between the working week and at the weekend could contribute to variability in sleep timing [38] and social jet lag [39,40]. Questionnaire measures such as the Sleep Timing Questionnaire [38] (STQ) could be used to quantify the components of sleep timing, as could measures derived from sleep diary parameters. We would define B as conventional (for a particular population) bedtimes and rise times, which are consistent (±1 h, at least four days a week).

For the remaining criteria, there seems to be some ambiguity as to the precise definitions. Furthermore, clear definitions are needed in order to standardize methods and measures. For example, we would interpret C as a currently diagnosable serious medical or

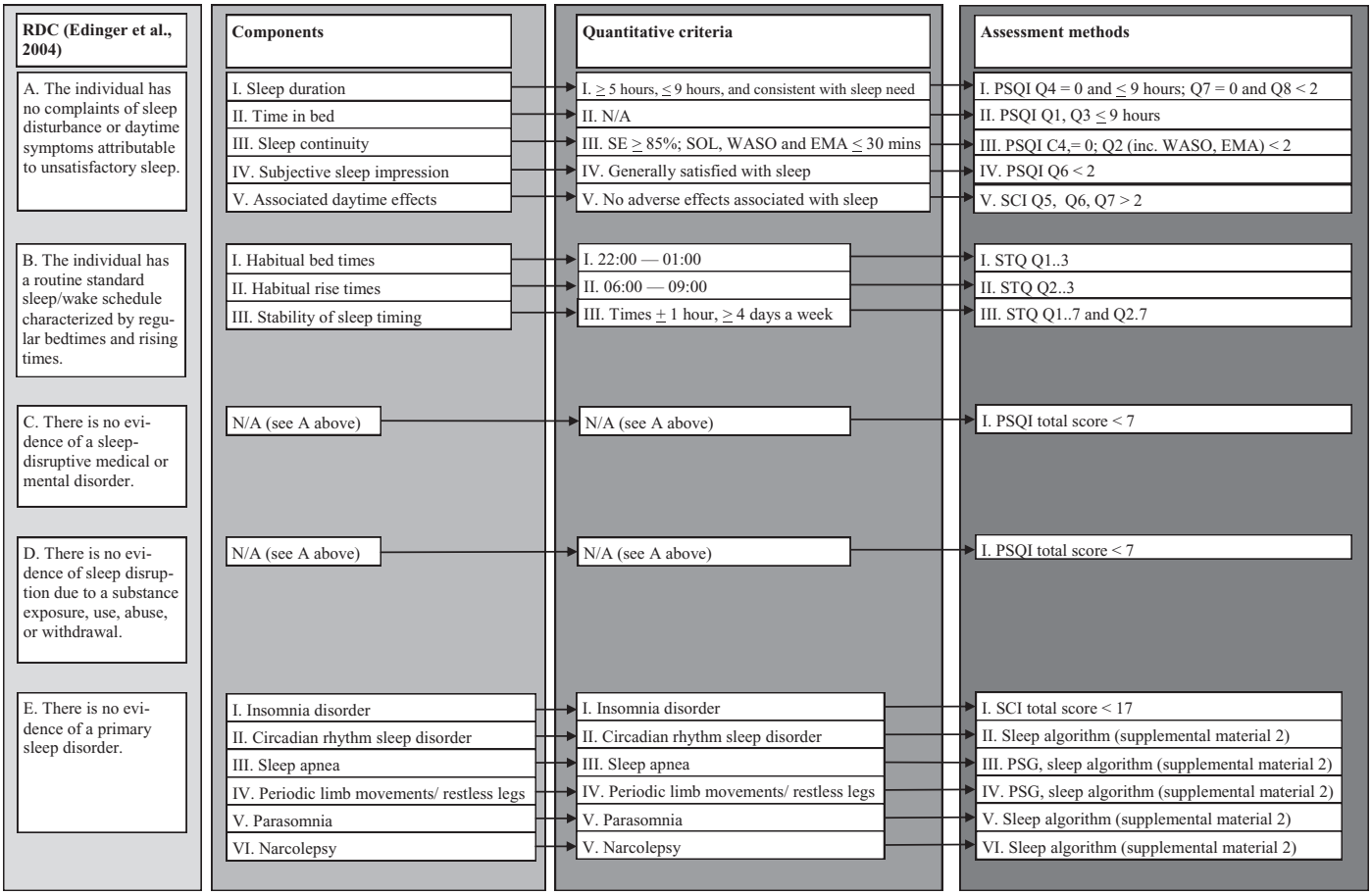

Fig. 2. Definition of normal sleep and assessment tools.

mental disorder. We would define Criterion D by the abuse of substances (eg, alcohol, caffeine, nicotine, or drugs), or by the use of prescription medication. Lastly, we would define E as a currently diagnosable sleep disorder, that is, narcolepsy/cataplexy, periodic limb movements or restless legs, parasomnias, CRSDs, and insomnia disorder, and in conjunction with PSG screening (e.g., for sleep apnea and periodic limb movements). Moreover, the presence of a significant health disorder, without associated sleep disruption, may be unlikely given the overlap of sleep with general health [1,41]. While the final three components (C, D, and E) seem particularly applicable within a medical setting, they may not be appropriate or necessary for use in all research settings, to ensure normal sleepers are selected.

4.1. *Defining normal sleep: a research agenda*

All of these components can be assessed in different ways, such as by simple self-reports (eg, do you have insomnia?), a personal history (eg, a previous diagnosis), evidence of symptoms (eg, screening measures or PSG), and a diagnostic clinical interview by trained experts. The precise levels of assessment applied would depend on, for example, the number of subjects to be tested, access to resources (eg, PSG and laboratory facilities), and the experience of the researcher (e.g., in diagnosing the presence of a disorder). To aid standardization across the field, we suggest that precise definitions, exclusion criteria, and descriptive information be reported as much as possible. Furthermore, the use of standardized methods, such as the consensus sleep diary [23], will help to aid comparisons between studies, as the precise contents of sleep diaries can vary between laboratories. In addition, Edinger et al. [2] recommend reporting information on the methods of recruitment and types of individuals, and the criteria for normal sleep may need to be tailored, for example, in elderly subjects [34]. Here, we suggest specific assessment tools thought sufficient to identify normal sleepers, favoring questionnaire methods, and aiming to reduce the burden on participants as much as possible (see Fig. 2).

Means, standard deviations, and ranges are also recommended to be reported for common sleep measures, as well as quantitative thresholds, and the measures from which these are derived. Indeed, we found sleep diaries to be often used, although full descriptive information, as stated above, was not always reported. Edinger et al. [2] report that most insomnia studies describe control subjects as being without sleep complaints or insomnia. Exclusions were found to be made for medical disorders that commonly affect sleep (~50%), symptoms of psychiatric disorder (~42%), psychoactive agents (~23%), evidence of sleep timing disruption (~15%), normal sleep values (~8.5%), or primary sleep disorders (<4%), and >85% of samples were selected based on less than three of these criteria, results that also appear broadly consistent with the present review. However, in our sample of primary or physiological insomnia patients and controls, these values are higher overall, and in both studies sleep timing measures are among the least reported. Here, we suggest a definition of normal sleep for use with control subjects in contrast to patients and in studies of healthy sleepers (eg, sleep deprivation paradigms). Furthermore, this may be of particular importance in student populations, whose sleep has been described as “erratic” [27].

With regard to specific criteria of normal sleep parameters, studies of insomnia have previously defined criteria for normal sleepers [29,42]. For example, papers may define sleep parameter thresholds for insomnia subjects, such as a sleep-onset latency or wake time after sleep onset duration of >30 min, total sleep time <6 h, and sleep efficiency <85% [42,43], and it could be possible to extrapolate criteria for normal sleepers from such reports. Furthermore, studies of sleep deprivation and epidemiological studies provide evidence of the effects of sleep manipulations and of normal ranges within the general population. In the absence of existing specifications for normal sleep, we would suggest the following definition and possible measurement tools.

First, an individual does not meet the criteria for an existing sleep disorder (ie, insomnia disorder, CRSD, sleep apnea, narcolepsy/cataplexy, periodic limb movements or restless legs syndrome, or a parasomnia). We suggest that the presence of periodic limb movements or restless legs syndrome and sleep apnea be assessed via PSG. Espie [44] has developed a screening algorithm for CRSD, parasomnias, restless legs syndrome or periodic limb movements, sleep apnea, and narcolepsy (Appendix S2). The ISI [6] can be used to assess the severity of insomnia symptoms in those with a sleep complaint, and sleep complaints together with daytime sleepiness may be indicative of a CRSD [45]. The sleep disorders questionnaire can also be used to assess sleep apnea, narcolepsy, and restless legs syndrome or periodic limb movements [46]. The diagnosis of narcolepsy without cataplexy was described in greater depth in 2014 [47]. In order to reduce the questionnaire burden on research participants, we suggest that the brief screening algorithm developed by Espie [44] be used to identify the likely presence of narcolepsy, parasomnias, and CRSDs, and used to confirm a lack of sleep apnea, periodic limb movements, or restless legs syndrome. However, the questions here are minimal, and PSG would provide a higher level of evidence. Furthermore, actigraphy can be used to assess CRSD, and the Sleep Condition Indicator [48] can be used to screen for insomnia disorder.

Second, an individual should not report any adverse daytime effects associated with poor sleep, at least within the previous week. Questionnaire measures could also be used to assess this, such as question 7 of the ISI [6] or component 7 of the PSQI [5]. Third, an individual should report general satisfaction with their sleep, which can be assessed via the subjective components of a sleep diary [23], component 1 of the PSQI [5], or question 4 of the ISI [6]. We suggest that question 6 of the PSQI – "During the past month, how would you rate your sleep quality overall?" – be used to assess general sleep satisfaction. For no adverse daytime effects of poor sleep, PSQI questions 7, 8, and 9 could be used, with complaints less frequently than once or twice a week. Alternatively, ISI question 3 could be used to assess this, as could questions 5, 6, and 7 of the Sleep Condition Indicator [48]. Fourth, we suggest specific definitions of sleep parameters to be indicative of normal sleep. In particular, we suggest thresholds for sleep duration, sleep continuity, time in bed, and sleep timing.

Typical sleep duration criteria are included, in keeping with a recent description of sleep health [49], and as short sleep duration/sleep restriction is linked to negative effects on health [1,41,50] and mortality [51]. Individuals with insomnia, who also have a short sleep duration, also seem to experience a more severe disorder (depression, heart and metabolic health) [52]. As an excessive sleep need, or time in bed, can be indicative of mood disorders [53], we would define normal sleep by a sleep duration of <9 h a night and >5 h a night (in the absence of diminished sleep continuity). Furthermore, the amount of sleep typically achieved should be consistent with sleep need (cf. Refs. [1,49]), and this is affected by factors such as age [27,34].

Sleep restriction also affects the ability to judge sleep need well [54]. For example, a study with "naturally short sleepers" found many potential subjects to report that their short sleep duration was associated with work or caregiving, or poor physical or mental health. Indicators of naturally short sleep duration included these sleepers not seeming to make up for lost sleep at weekends and having identical Epworth Sleepiness Scale (ESS) scores as control subjects. These subjects slept on average for ≤6 h a night, and they were found to show significantly greater evidence of hypomanic symptoms [55]. These studies taken together indicate that there are few people who are naturally short sleepers and those who show evident signs of mood disruption. However, these guidelines will require testing, and ultimately there will be a trade-off between sensitivity and specificity. We would suggest that sleep timing be assessed via questions 1 and 3 of the PSQI or via the STQ [38]. Sleep duration could be assessed via the PSQI, with question 8 (daytime sleepiness) used to assess whether sleep need is being met. These measures combined implicitly set limits on time in bed.

On measures of sleep continuity, sleep-onset latency, wake time after sleep onset, and early-morning awakenings should each be <30 min, with a sleep efficiency of >85%. These components can be assessed via sleep diary [23] or the PSQI [5]. With regard to sleep scheduling, ordinarily, the timing of sleep should be consistent with a 9 am to 5 pm work pattern. We would suggest a typical bedtime of 22:00–01:00, with a rise time of 06:00–09:00. Furthermore, these times should not vary markedly, with sleep times being consistent, within an hour, most days a week. The STQ [38] and sleep diaries [23] can be used to assess sleep timing and stability. However, ideally, all components of normal sleep could be captured by the use of a single measure, and sleep diaries are not always practical. While a comprehensive definition of good sleep in contrast to normal sleep is beyond the scope of the present review, we suggest documenting applied criteria, to allow for future work in this area (see Fig. 3). Furthermore, these components are consistent with those recently identified by Buysse [49] (sleep duration, efficiency/continuity, timing, alertness, and satisfaction), as being important for sleep health. A sleep health questionnaire was also described [49].

Additional criteria might be needed for the screening/selection of good sleepers, such as the endorsement of good sleep, alongside the absence of complaint. Good sleepers and normal sleepers could be somewhat different subject groups, and this could be worth investigating further. For example, three hypotheses may be made based on their differences. First, good sleepers may be less likely to report or experience sleep disruption. Second, the effects of sleep loss on daytime functioning could be less severe, or minimal, for good sleepers. Third, good sleepers could have a general resilience against poor health and towards well-being. For example, the Ford Insomnia Response to Stress Test (FIRST) can be used to assess vulnerability towards sleep disruption [56], and the importance of sleep adaptability has been recognized theoretically [25,49]. Understanding this resilience to poor sleep/insomnia could have important implications for individuals and organizations, where sleep disruption may be expected.

As a result of this review, we have developed the Revised Research Criteria for Defining Normal Sleeper Controls (Fig. 3) for use with control subjects. Here, we suggest four main components of normal sleep, that is, sleep disruption, circadian disruption, sleep disorders, and general health, which includes each of the five components previously identified [2]. We would define sleep quality with the following three subcomponents: sleep duration and continuity, subjective sleep impression, and its impact on functioning. Sleep timing includes habitual bedtimes and rise times, their impact, and sleep timing stability. With regard to other sleep disorders, four key sleep disorders are most relevant to screen for: narcolepsy/cataplexy, sleep-disordered breathing or sleep apnea, parasomnias, and restless legs and periodic limb movements. Insomnia disorder and CRSDs can be assumed to be covered within sleep quality and sleep timing

		Yes/ No	Levels*	Definitions/ exclusions
1. Sleep quality	Sleep duration		0 1 2 3 4	*≥ 6 hours, consistent with sleep need*
	Time in bed		0 1 2 3 4	*≤ 9 hours*
	Sleep continuity		0 1 2 3 4	*SE ≥ 85%; SOL, WASO, EMA ≤ 30 mins*
	Subjective sleep impression		0 1 2 3 4	*Generally satisfied*
	Associated daytime effects		0 1 2 3 4	*No adverse effects*
2. Sleep timing	Habitual bed times		0 1 2 3 4	*22:00 — 01:00*
	Habitual rise times		0 1 2 3 4	*06:00 — 09:00*
	Stability of sleep timing		0 1 2 3 4	*± 1 hour, ≥ 4 days a week*
	Associated daytime effects		0 1 2 3 4	*No adverse effects*
3. Sleep disorders	Insomnia disorder		0 1 2 3 4	*e.g. PSQI < 7*
	Circadian rhythm sleep disorder		0 1 2 3 4	*e.g. sleep algorithm*
	Sleep apnea		0 1 2 3 4	*e.g. PSG, sleep algorithm*
	PLMS/ RLS		0 1 2 3 4	*e.g. PSG, sleep algorithm*
	Narcolepsy		0 1 2 3 4	*e.g. sleep algorithm*
	Parasomnia		0 1 2 3 4	*e.g. sleep algorithm*
Optional:				
4. General health	Physical health		0 1 2 3 4	*e.g. cardiovascular disease*
	Mental health		0 1 2 3 4	*e.g. DSM-IV disorders*
	Medication use		0 1 2 3 4	*e.g. prescription medication*
	Substance abuse		0 1 2 3 4	*e.g. alcohol, nicotine, caffeine, recreational drugs*

***Levels**

0 = N/A

1 = simple self reports	e.g. are you a satisfied with your sleep? (Y/N)
2 = personal history	e.g. past diagnosis, family history
3 = evidence of symptoms	e.g. questionnaires, PSG, blood work
4 = diagnosable disorder	e.g. expert—diagnosed disorder (screening interview)

Fig. 3. Revised research diagnostic criteria for defining normal sleeper controls.

(see Image 3). Under general health, we combined C and D of the RDC, and included mental and physical health with medication use and substance abuse. However, extreme levels of substance abuse would overlap with mental health (ie, at the level of a substance abuse disorder), and substance abuse would include illicit drugs as well as, for example, nicotine, alcohol, and caffeine.

In summary, while results suggest that in general the methods of assessing normal sleepers cover the key components of normal sleep as specified by Edinger et al. [2], there is variability in the exact procedures used by different laboratories. However, an important limitation of the present results is that review papers used a well-defined insomnia sample, and results may differ if a broader inclusion criterion was used. It should also be noted that some of the studies reviewed may have begun before the publication of the RDC in 2004, and they were published afterwards. Nonetheless, even within the current sample, important issues in identifying controls were identified. Different fields could also apply different definitions to normal sleepers/control subjects, and we agree with Edinger et al. [2] that "due to this lack of standardization, synthesizing results of multiple. . .studies is a difficult if not impossible task." As a first step, greater reporting of descriptive sleep information would aid in clarifying the exact nature of control groups. If screening of sleep disruption and timing can be clarified, additional methods could be redundant, and this would help reduce the burden on controls. While existing measures, such as the PSQI [5] and ISI [6], provide ranges for a lack of sleep disruption, these measures are not used consistently. Furthermore, as predominately global measures, these questionnaires do not tend to be reported at the item level, and they do not address all components of the RDC [2]. The use of these criteria for normal sleep would help clarify how the components of the RDC are assessed, aiding the understanding of how insomnia develops, as well as the nature of good sleep itself, by helping to standardize this field.

Conflict of interest

Professor Colin Espie is the clinical and scientific director of Sleepio Limited. The present study was conducted at the University of Glasgow, School of Psychology, and it was not funded by or connected to Sleepio Limited.

The ICMJE Uniform Disclosure Form for Potential Conflicts of Interest associated with this article can be viewed by clicking on the following link: http://dx.doi.org/10.1016/j.sleep.2015.01.010.

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Appendix: Supplementary material

Supplementary data to this article can be found online at doi:10.1016/j.sleep.2015.01.010.

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